REMARKS

Rejection under 35 USC 112

Examiner rejected claim 1 under 35 USC 112, second paragraph.

Per Examiner's requirement, "said conduit" has been amended to read "a conduit." Therefore, Applicant believe this rejection has been overcome.

Rejection under 35 USC 102 – Bao et al.

Examiner rejected claims 1, 6-20, 99 and 101 under 35 USC 102(b).

Applicant submits that the claims are novel over Bao by recitation of the following features:

"wherein said first end is implanted into the intervertebral disc, and said second end of said conduit is implanted into a muscle, thereby re-establishing exchange of waste and nutrients between the intervertebral disc and muscle"

Background & summary of the invention by Bao 6,224,630

Back pain can be caused by herniated disc **2**, leaking nucleus pulposus **5** through a hole or aperture **4** to impinge adjacent nerve. Bao 6,224,630 invented a plug **10** to seal the aperture **4** to prevent nucleus pulposus **5** from leaking to cause re-herniation. The plug **10** fits, seals or expands tightly in the aperture **4** of the annulus **3** of the disc **2**.

Location of the plug **10** is utmost important for alleviating back pain. One end **15** of the plug **10** is located in the disc **2**, and another end **16** of the plug **10** is at the surface of the repaired disc **2**, as shown in Figures 2, 4-5. Extension of the plug **10** outside the disc **2** would impinge nerve, resulting in excruciating pain, similar to a herniated disc.

Background & summary of invention in US 10/555,895

Surprisingly, 85% of back pain patients show no nerve impingement under MRI or CT.[1-2] In fact, disc protrusion and herniation accounts for less than 5% of all low back pain.[3] The cause of most chronic back pain perplexes both physicians and patients.

Figure 1 shows the disc is avascular (no blood vessels or nerves). Oxygen and nutrients essential to disc cells are diffused from vascular buds at endplates into the disc.[4-6] However, diffusion of oxygen and nutrients is shallow, less than 2 mm into human discs (Figure 2), which can be 8-12 mm thick,[7-8] resulting in anaerobic production of lactic acid especially in the mid-layer of the disc (Figure 3). Diffusion is further hindered by accumulation of calcified layers at the endplates, occluding many vascular buds. Disc specimens from surgeries are acidic, 15-50X acidity of blood. Leakage of the acid from fissures to surrounding nerves causes excruciating pain, even scarring nerve roots to cause chemical radiculitis.[9-11]

Conduit **126** is a highly biocompatible wick or filament, bridging between the acidic disc **100** and muscle **193** (Figures 86-87, 92) or vertebral body **159** (Figures 45, 48, 51-53, 91). When disc pressure is high from gravity and compression, lactic acid solution in disc is expelled through the conduit into muscle or vertebral body. When disc pressure is low at sleeping position, oxygen, nutrients and pH buffer in plasma of muscle or vertebral body are drawn through the conduit **126** into the avascular disc **100** to neutralize the lactic acid.

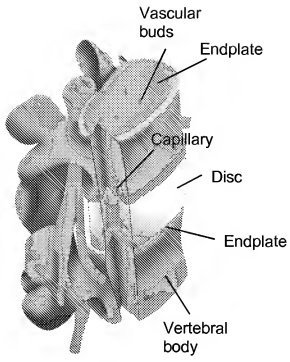


Figure 1

Diffusion of oxygen & nutrients from vascular buds into disc.

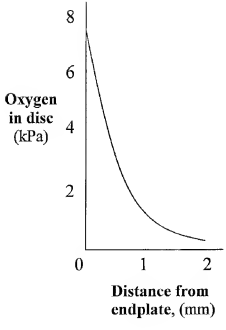


Figure 2

Shallow diffusion of oxygen into disc

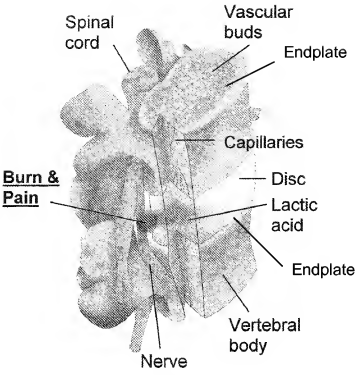


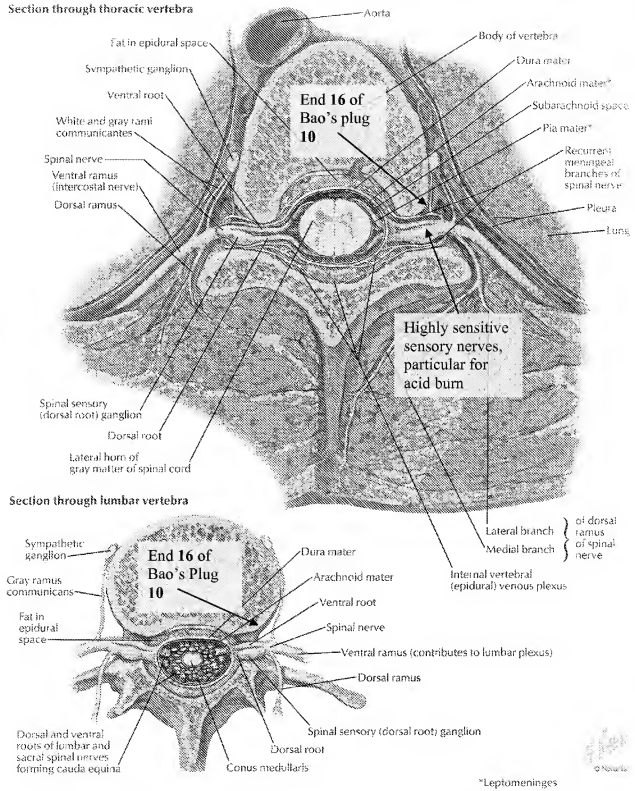
Figure 3

Lactic acid from anaerobic metabolism leaks and causes persistent pain.

Embodiment of Bao 6,224,630

The plug **10** of Bao 6,224,630 needs to be large to seal and occlude the aperture **4** in the annulus **3** of the disc **2**. The large plug **10** cannot extend from the disc **2**, otherwise the plug **10** would impinge the spinal nerve, causing excruciating pain. Please see the spinal structures below.

Secondly, the plug **10** is not an embodiment for drawing lactic acid from the disc **2** to dispose into bodily circulation. The second end **16** of the short plug **10** (Figures. 5 and 2) is located at the surface of the disc **2**, approximating the spinal nerve. If the plug **10** has fluid drawing capability, lactic acid solution in the disc **2** would be dumped directly on the spinal nerve, causing excruciating pain from acid burn. But "lactic acid" or "waste" is not mentioned in Bao 6,224,630. Hence, the plug **10** does not have the embodiment to dispose lactic acid or waste to treat back pain. Please see the spinal structures below.


Section through thoracic vertebra
Aorta
Fat in epidural space
Body of vertebra
Dura mater
Sympathetic ganglion
Arachnoid mater*
Ventral root
End 16 of Bao's plug 10
Subarachnoid space
White and gray rami communicantes
Pia mater*
Recurrent meningeal branches of spinal nerve
Spinal nerve
Ventral ramus (intercostal nerve)
Dorsal ramus
Pleura
Lung
Highly sensitive sensory nerves, particular for acid burn
Spinal sensory (dorsal root) ganglion
Dorsal root
Lateral horn of gray matter of spinal cord
Section through lumbar vertebra
Lateral branch
Medial branch
of dorsal ramus of spinal nerve
Sympathetic ganglion
End 16 of Bao's Plug 10
Dura mater
Internal vertebral (epidural) venous plexus
Gray ramus communicans
Arachnoid mater
Ventral root
Fat in epidural space
Spinal nerve
Ventral ramus (contributes to lumbar plexus)
Dorsal ramus
Spinal sensory (dorsal root) ganglion
Dorsal and ventral roots of lumbar and sacral spinal nerves forming cauda equina
Dorsal root
Conus medullaris
*Leptomeninges

Embodiment of US 10/555,895

Unlike the embodiment of the annular sealing plug **10** of Bao, the conduit **126** in US 10/555,895 extends from disc **100** into the vertebral body **159**, as shown in Figures 48-49, 51-53. The conduit **126** of US10/555,895 can also extend from disc **100** into muscle **193**, as shown in Figures 86, 88 and 92.

The amended claims include precise locations of the conduit **126**, thereby the exchange of waste and nutrients between disc **100** and muscle or vertebral body is re-establish to relive back pain.

Embodiment and location of the plug of Bao 6,224,630 are designed to seal the disc:

Abstract A surgical device and related method and kit for use in sealing a biological aperture in situ. In one embodiment, the device is provided in the form of an expandable, porous material such as poly(vinyl alcohol).

Claim 1. A device for sealing a biological aperture in situ, the device comprising a porous, expandable material adapted to be sealably positioned within the biological aperture and to permit natural tissue ingrowth into the device, wherein the aperture is in the annulus of an intervertebral disc.

Claim 9. A device according to claim 7 wherein the device is adapted to be used in combination with a biomaterial delivery cannula, in order to seal the cannula access aperture formed in the annulus in the course of delivering a curable biomaterial to the nucleus.

Claim 10. A method for sealing a biological aperture in situ, the method comprising the use of a device comprising a porous, expandable material adapted to be sealably positioned within the biological aperture and to permit natural tissue ingrowth into the device, wherein the aperture is in the annulus of an intervertebral disc.

Claim 23. A device for sealing a biological aperture in situ, the device comprising a porous, expandable material adapted to be sealably positioned within a biological aperture and to permit natural tissue ingrowth into the device, wherein the aperture is provided in the annulus of an intervertebral disc, the material comprises poly(vinyl alcohol), and the device is adapted to be delivered to and positioned within the aperture, in conformity with the dimensions of the aperture, using minimally invasive techniques.

Claim 32. A device according to claim 25 wherein the material is adapted to be secured or anchored into the aperture using biodegradable sutures, staples, fibrin sealants, or surgical glues.

Claim 53. A method according to claim 46 wherein the material is adapted to be secured or anchored into the aperture using biodegradable sutures, staples, fibrin sealants, or surgical glues.

Column 2, Lines 48-54: Although a number of prosthetic intervertebral discs, nuclear implants, and disc spacers are known in the art, relatively little attention has been focused on effectively sealing an opening in the annulus which has either been initiated surgically, such as an access port for a minimally-invasive technique, or caused naturally, as in the case of herniation.

Column 2, Lines 58-64: Summary of The Invention The present invention provides a device and related method for sealing biological apertures (e.g., orifices, holes, clefts, tears, and openings) in situ, such as an annular tear or disc herniation site, the device comprising a material adapted to be sealably positioned within the aperture and to permit natural tissue ingrowth, such as fibrous tissue ingrowth, into the device.

Column 4, Lines 35-37: The invention relates to a device and method (e.g., minimally invasive method) for sealing biological apertures in situ, such as an annular tear or disc herniation site.

Column 5, Lines 14-19: Accordingly, by using the device of the invention, the aperture in the annulus can be sealed and biocompatibility of the implant assured, while the disc itself is provided with sufficient short- and long-term mechanical support and function.

Column 5, Lines 20-30: As can be seen from FIGS. 1 and 2, the device 10 is illustrated as being adapted for insertion into the intervertebral disc 2 of the spine 1. In particular, the device 10 is adapted for insertion into an aperture 4 located in the annular portion 3 of the disc 2 such that the peripheral surface 11 of the device 10 contacts the intact tissue surrounding the aperture 4 thereby both sealing the annulus 3 in a manner sufficient to prevent extrusion of the inner material of the nucleus 5, and to inhibit migration of the device within or from its placed position.

Column 7, Lines 61-67: A device can have other structural features unique to its application. For instance, a cylindrical plug, for use in sealing an annular aperture, can be provided with one or

more expanded or enlarged end portions (forming a mushroom-, spool-like or anvil-like configuration) in order to prevent migration of the plug and better contain nuclear material.

Column 8, Lines 4-9: Expansion of the annular plug device results in a taught circumferential sealing of the access port. Accordingly, the device can induce further tissue ingrowth into the nuclear region as well as the peripheral annular region so as to provide further mechanical support to the disc.

Column 8, Lines 44-49: Accordingly, the width of the expanded device is sufficient to conform to the width of the aperture 4 in the annulus 2, such that the device 10 both seals the annulus in a manner sufficient to prevent extrusion of the inner nucleus material, and to inhibit migration of the device within or from its placed position.

Column 11, Lines 24-27: Additionally, if an expandable biomaterial is used, the surgically-created access port is sealed after implantation of the prosthesis. Accordingly, the device also facilitates the healing of the annulus after surgery.

Column 14, Lines 22-28: Examples of such surgical fixation techniques include, but are not limited to, biodegradable sutures, staples, fibrin sealants, surgical glues and the like. When suturing techniques are used to secure the device in the annulus, for example, the ends of the device can be sutured together with the adjacent annular tissue surrounding the aperture.

Embodiment and location of the plug of Bao 6,224,630 are designed to mechanically support the disc:

Column 5, Lines 15-19: Accordingly, by using the device of the invention, the aperture in the annulus can be sealed and biocompatibility of the implant assured, while the disc itself is provided with sufficient short- and long-term mechanical support and function.

Column 8, Lines 6-9: Accordingly, the device can induce further tissue ingrowth into the nuclear region as well as the peripheral annular region so as to provide further mechanical support to the disc.

Column 8, Lines 61-65: The elongated structure offers the advantage of providing support to the entire posterior or lateral portion 7 of the annulus, thereby forming an even wider wall or barrier which affords support and prevents herniation over a wider area of the disc 2.

Column 10, Lines 40-44: In one embodiment as depicted in FIG. 6, the device 10 includes discrete internal and external portions 20 and 21, respectively, wherein the internal portion 20 is provided in the form of a semi-rigid material used to provide mechanical support.

Column 11, Lines 33-37: In their contracted (or unexpanded) form, preferred materials can be adapted for substantially minimally invasive introduction to the tissue site, where upon expansion, they serve to secure the device in place and provide immediate structural support.

Column 11, Lines 58-64: Taught and secure positioning of the device within the aperture affords immediate structural support to the tissue. Such support is especially important at tissue injury sites prone to hydrostatic forces, for example the annulus of the intervertebral disc, where the device prevents short-term herniation of the nucleus pulposus from the interior portion of the disc.

Column 12, Lines 24-31: As a result, an aperture in the annular wall is created which is compatible with the configuration of the device. In the case of a disc which is compressed or has a weakened annular portion, one or more apertures can be provided in the portion(s) of the annulus that require the most structural support or adjustment.

Column 14, Lines 39-42: Another aspect of the invention relates to a method of repairing and supporting the intervertebral disc in a patient using the implantable annular device, including a method of repairing a herniated disc using the device.

Claim 19. A device according to claim 18 wherein the regions are provided in the form of internal and external portions wherein the internal portion is provided in the form of a semi-rigid material used to provide mechanical support.

Claim 42. A method according to claim 41 wherein the regions are provided in the form of internal and external portions wherein the internal portion is provided in the form of a semi-rigid material used to provide mechanical support.

Rejection under 35 USC 103 – Bao et al. and Mickley

Examiner rejected claims 2-5, 24-33, 35-40, 45-49, 51-54 and 100 under 35 USC 103(a) based on Bao et al. and Mickley.

Rejection under 35 USC 103 – Bao et al., Mickley and Gough

Examiner rejected claims 2-5, 24-33, 35-40, 45-49, 51-54 and 100 under 35 USC 103(a) Bao et al., Mickley and Gough.

Rejection under 35 USC 103 – Bao et al.

Examiner rejected claim 23 under 35 USC 103(a) based on Bao.

Rejection under 35 USC 103 – Bao et al., Mickley and Makower et al.

Examiner rejected claim 34 under 35 USC 103(a) based on Bao et al. Mickley and Makower et al.

Rejection under 35 USC 103 – Bao et al., Mickley and Rowland

Examiner rejected claim 41-44 under 35 USC 103(a) based on Bao et al. Mickley and Rowland

As with Bao which is discussed in detail above, none of the additional prior art cited in combination with Bao, including Mickley, Gough, Makower et al. and Rowland, discuss the claimed feature of:

"wherein said first end is implanted into the intervertebral disc, and said second end of said conduit is implanted into a muscle, thereby re-establishing exchange of waste and nutrients between the intervertebral disc and muscle"

Therefore, Applicant submits that all of the claims are patentable over the prior art. Allowance of the claims is respectfully requested.

List of Citations Footnoted in the Remarks

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2. Boswell MV, et. al.: Interventional Techniques: Evidence-based practice guidelines in the management of chronic spinal pain, Pain Physician, 10:7-111, ISSN 1533-3159, 2007.
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11. Keshari KR, Lotz JC, Link TM, Hu S, Majumdar S, Kurhanewicz J: Lactic acid and proteoglycans as metabolic markers for discogenic back pain, Spine, Vol. 33(3):312-317, 2008.

CONCLUSION

For all the reasons above, Applicant submits that the claims all define novel subject matter that is nonobvious. Therefore, allowance of these claims is submitted to be proper and is respectfully requested.

Applicant invites the Examiner to contact Applicant's representative as listed below for a telephonic interview if so doing would expedite the prosecution of the application.

Very respectfully submitted,

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